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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,819	06/04/1999	MAKOTO YAMAMORI	85765-000000	3326

20350 7590 02/12/2002

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EXAMINER

GRUNBERG, ANNE MARIE

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 02/12/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/325,819**Applicant(s)  
**Makoto Yamamori**Examiner  
**Anne Marie Grunberg**Art Unit  
**1661**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Nov 27, 2001.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-5 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-15 are pending. Claims 6-15 were not elected. Applicant is reminded to cancel claims 6-15 because they are drawn to an unelected invention(s). Claims 1-5 have been examined.

Applicant is reminded to file substitute drawings in accordance with the draftsman's comments attached to Paper #10.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections***

1. Claims 1-5 remain rejected under 35 U.S.C. 112, first paragraph for the reasons stated in the last office action.

Applicant states that the deposit requirement has been met because the seeds have been deposited in the genebank of the National Institute of Agrobiological sciences. However this depository is not an accepted IDA (see MPEP 2405). There are two ways in which the 112 enablement rejection can be overcome: by proving that the material is known and readily available, or by deposit as described in the last Office Action. Since the material has not been deposited in the appropriate manner, the Examiner assumes that the Applicant is relying on 37 CFR 1.802(b) which states that biological material need not be deposited if it is known and readily available to the public.

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Applicant provides a certificate certifying that seeds of the parent varieties were deposited in a genebank. The certificate further certifies that the seeds were tested for viability and found viable, that the seeds will be preserved at least until 2030 A.D., and that the seeds are publicly available. Applicant further provides information pertaining to the Genebank.

This information has been considered, but is not deemed adequate for the following reasons. A deposit may not be required if the biological material is both known and readily available to the public - neither concept alone is sufficient. A material may be known in the sense that its existence has been published, but is not available to those who wish to obtain that particular known biological material. Likewise, a biological material may be available in the sense that those having possession of it would make it available upon request, but no one has been informed of its existence (MPEP 2401.01).

In *Ex parte Humphreys*, 24 USPQ2d 1255 (Bd. Pat. App. & Int. 1992), the Board held that a deposit of bacteria at the John Innes Institute did not provide availability to the public. Even though in this case, Applicants were able to prove that others were able to obtain the material from the establishment prior to and after the present filing date, it did not establish that upon issuance of a patent that such material would continue to be accessible to the public. In this case, the Applicants did not make of record any of the facts and circumstances surrounding their obtention of material from the John Innes Institute, nor was there any evidence as to what the policy would have been upon issuance of a patent. There was no indication on the record that the Institute would allow unlimited access to the public.

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There are many factors that may be used as indicia that a biological material is known and readily available to the public. Relevant factors include commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, or an existing deposit made in accordance with specified rules. Each factor alone may or may not be sufficient to demonstrate that the biological material is known and readily available.

The office will accept commercial availability as evidence that a biological material is known and readily available only when the evidence is clear and convincing that the public has access to the material. The relationship between the applicant relying on a biological material and the commercial supplier is one factor that would be considered in determining whether the biological material was known and readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under specified rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that **all restrictions on the accessibility be irrevocably removed by the Applicant upon the granting of the patent**. See MPEP 2404.01 for a more in depth discussion of known and readily available.

In the instant case, Applicant has not met the burden of establishing that the biological material is known and readily available to the public. The Examiner notes that the Certificate of

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Wheat Seeds states that the seeds are publicly available *if required*. It is not clear what this statement exactly means nor is it clear as to what constitutes requirement.

It has also not been established that all restrictions to accessibility will be irrevocably removed by the Applicant upon the granting of the plant.

Additionally, Applicant has not made of record any of the facts and circumstances surrounding obtention of material from the Genebank nor is there any evidence as to what its policy is in this regard, either now or in the future if a patent were to issue on this application. On the record there is no assurance that the Genebank would allow unlimited access to the wheat seeds if this application were to mature into a patent.

Since Applicant has failed to overcome the 112, first paragraph rejection by depositing the seeds in accordance with the manner specified in the last Office Action and alternatively, because Applicant has failed to make a convincing argument that the biological material is **both** known and readily available, the enablement rejection is maintained.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grunberg whose telephone number is (703) 305-0805. The examiner can normally be reached Monday through Friday from 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (703) 308-4205. The fax phone number for this group is (703) 308-4242.

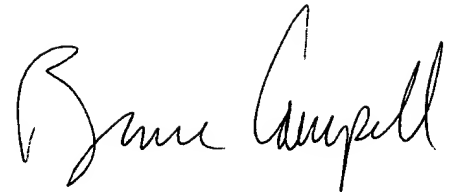
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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AMG

A handwritten signature in black ink, reading "Bruce Campell". The signature is written in a cursive style with a large, stylized "B" and "C".

**BRUCE R. CAMPELL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**